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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/560,961	05/30/2006	Marie Eskling	BNIT0005PCT-US	9435

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LAW OFFICE OF SALVATORE ARRIGO
1050 CONNECTICUT AVE. NW
10TH FLOOR
WASHINGTON, DC 20036

EXAMINER

BASI, NIRMAL SINGH

ART UNIT	PAPER NUMBER
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1646

NOTIFICATION DATE	DELIVERY MODE
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11/18/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

SAL@ARRIGO.US

Office Action Summary	Application No. 10/560,961	Applicant(s) ESKLING ET AL.	
	Examiner NIRMAL S. BASI	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 26 May 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) 1-35, 45 and 47-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 36-44, 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>8/6/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment filed 5/26/09 has been entered. Applicant has amended claims 36, 38-44 and added new claim 54. Claims 1-35, 45, 47-53 are withdrawn. Claims 36-44, 46 and 55 are examined below as they pertain to the elected invention.
2. IDS filed 8/6/09 has been entered and considered.

Claim Rejections - 35 USC . 101

3. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 36, 37 and 54 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 36, 37 and 54 recite nucleic acid fragments but do not recite that they are isolated or purified. The claims as currently recited encompass these naturally-occurring compounds. Therefore, the compounds as claimed are a product that occurs in nature and does not show the hand of man, and as such is non-statutory subject matter. It is suggested that the claims be amended to recite "An isolated and purified nucleic acid fragment" to overcome this rejection.

Claim Rejection, 35 U.S.C. 112

4. Claims 36-44, 46 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 36 and 54 are indefinite because it is not clear what is an “immunogenic variant” so as to allow the metes and bounds of the claim to be determined. The term “immunogenic variant” carries no weight in terms of structure and function and encompasses an unlimited number of alterations and reads on unrelated molecules. Therefore, the metes and bounds of the claim cannot be determined.

Claims 36 and 54 are indefinite because it is not clear if the variant is the nucleic acid fragment that encodes the protein that comprises the amino acid sequence of residues 17-677 of SEQ ID NO:2 or if the nucleic acid fragment encodes proteins that are variants of the protein that comprises the amino acid sequence of residues 17-677 of SEQ ID NO:2. What word does the “variant” modify.

Claims 37, 38, 39, 40, 41, 42, 43, 44, 46 are indefinite for depending on an indefinite base claim and fail to resolve the issues raised above.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

5. Claim 36-44, 46 and 55 rejected under 35 U.S.C. 102(b) as being anticipated by M & E Biotech (WO 00/20027, see IDS).

M & E Biotech discloses HER-2 (SEQ ID NO:3) which is a nucleic acid fragment that encodes an immunogenic variant of HER-2 protein that comprises or consists of the

Art Unit: 1646

amino acid sequence set forth in SEQ ID NO:2, residues 17-677. Further, M & E Biotech discloses (see pages 74-77, 91-97) vectors carrying the HER-2 variants. Vectors that are plasmid, phage, cosmid and virus. Immunogenic composition comprising said vector. Vector that is capable of autonomous replication. Vector comprising promoter, leader peptide and said nucleic acid fragment. Host cell transformed with said vector. The disclosure of M & E Biotech meets the limitations of claims 36-44, 46 and 55 absent evidence to the contrary.

Instant specification on pages 16 and 17 acknowledges that the HER2 disclosed by M & E Biotech is a variant of SEQ ID NO:2. The specification discloses:

“HER-2 variant of the invention

As mentioned above, the present inventive method has been conceived when purifying a variant of the human HER-2 tumour antigen. This particular variant has proven to be especially well-suited as a vaccine agent for inducing immunological reactions against autologous HER-2 so this particular variant is also a part of the present invention.

In general, the specific use, formulation, recombinant production, suitable vectors and host cells as well as other details pertaining to this specific HER-2 variant can be found in the disclosure of WO 00/20027. Hence, in the following only a brief discussion will be provided that specifically pertains to the variant. Hence, the disclosure of WO 00/20027 is included by reference herein and provides for the necessary teachings concerning immunization with HER-2 variants and the general methods for producing these and their formulation. Also the disclosure in WO 00/20027 relating to nucleic acid vaccination against autologous HER-2 is incorporated by reference herein. “

6. No claim is allowed

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

Art Unit: 1646

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NIRMAL S. BASI whose telephone number is (571)272-0868. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1646

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Nirmal S. Basi/

Examiner, Art Unit 1646

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646